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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,549	11/21/2001	Gyula Vigh		2580

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,549

Applicant(s)

VIGH, GYULA

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27-30, 33, 39-41 and 43-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Bier et al (USP 4,204,929). The use of Bier as an anticipatory teaching again for the claims was necessitated by the new claims.
3. Bier discloses an isoelectric gateway for altering the composition of a sample that comprises a number of ion-permeable barriers 52-60 any number of which would read on the specified first and second ion-permeable barriers that are a predetermined distance apart from each other (col. 8, ll. 11-51). Between each of the various ion-permeable barriers are isoelectric substances (col. 1, ll. 28-46). With respect to the ion-permeable barriers substantially retaining the isoelectric substances between the barriers, this would appear to be an inherent feature of any isoelectric focusing apparatus including the apparatus of Bier. In particular, isoelectric focusing relies on the establishment of a gradient where each chamber between the ion permeable barriers has a characteristic pH value, which is established and maintained by the presence of an isoelectric substance having a characteristic pI value. See col. 1, ll. 28-46. Because the pH in each of the chambers remains substantially constant (see table I) and because the isoelectric substances will remain at a pH value that matches the substances pI value, the isoelectric substance will remain substantially between two given ion permeable barriers, giving the term

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“substantially” its broadest reasonable interpretation. See also col. 4, ll. 4-6 and col. 5, ll. 38-42 where Bier teaches away from any convective flow. Bier also does not disclose binding the isoelectric substances to the ion permeable barriers thereby meeting those limitations as well.

4. With respect to choice of ion-permeable barriers, Bier teaches porous non-ionic membranes. See col. 7, ll. 32-65.

5. With respect to claims 30 and 33, these claims only further limit claim 29 when frit or gel is chosen from claim 29. Because these claims don't require gels or frits be chosen from claim 29, they don't further limit claim 29 when non-ionic membranes are chosen from claim 29.

6. With respect to whether the isoelectric substance is flowing or stationary, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

7. With respect to the pI value for the isoelectric substance, table I evidences that the pI of the isoelectric substances would clearly fall in the broadly defined range.

8. With respect to the method of claim 43, Bier already established the set forth structure of the method (see discussion above), and Bier further discloses applying a selected potential across associated electrodes positioned on opposing side of the isoelectric gateway to cause migration of at least one amphoteric compound to migrate through one of the ion-permeable barriers. See col. 7, ll. 4-12, table I, and col. 11, l. 49 through col. 12, l. 64.

9. With respect to claim 44 (those limitations not covered above), Bier also discloses the presence of first and second electrolyte chambers (19,20) and numerous sample chambers (formed by membranes 52-60) and any number of these formed chambers would read on the claimed first and second chambers of the claims. The various membranes (or barriers 15 or 16)

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also constitute the claimed first and second ion-permeable barriers or the first and second selective barriers (i.e. the barriers effectively selective based on the isoelectric point of the sample being analyzed). Bier further discloses means for communicating first and second electrolytes to the first and second electrolyte chambers and for communicating first and second fluids to the first and second sample chambers (paragraph bridging cols. 9 and 10). Bier also discloses a means for applying a selected electric potential to cause migration through the ion permeable membranes (col. 10, ll. 12-15).

10. With respect to a pH gradient, see Table I.

11. With respect to the various claimed third, fourth, fifth and/or six barriers (or second or third isoelectric gateways), Bier discloses a total of 9 different barriers 52-60 which are ion-permeable and formed isoelectric gateways. In addition, Bier also discloses two specifically ion-permeable barriers 15 and 16. Finally, col. 7, ll. 32 and 33 indicates that more barriers can even be added (thereby forming more isoelectric gateways).

12. With respect to the method of isoelectric focusing, see the rejection of claim 43 above and the rejection of the various structural elements of the claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 in view of Perry et al (USP 5,087,338).

15. Bier set forth all the limitations of the claim, but did not explicitly recite the use of the set forth groups. Perry teaches in an alternate electrophoresis apparatus that suitable membranes can be constructed from cellulose esters and polysulfones (col. 7, ll. 60-65). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Perry for the apparatus of Bier because the substitution of one known membrane material for another requires only routine skill in the art.

16. Claims 30-33 in the alternative are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 in view of Dubrow (USP 5,164,055).

17. With respect to claim 33 in the alternative, Bier set forth all the limitations of the claim, but did not explicitly recite the use of a frit for forming ion-permeable barriers. Dubrow teaches in an alternate isoelectric focusing apparatus that glass frits are a known material for controlling fluid movement across a barrier (col. 4, ll. 3-5 and col. 10, ll. 52-62). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Dubrow for the apparatus of Bier because frits are a known barrier material and the substitution of one known barrier material for another requires only routine skill in the art.

18. With respect to claims 30-32, these claims merely further limit either the gels or non-ionic membranes of claim 29. Because these claims don't require gels or non-ionic membranes be chosen from claim 29, they don't further limit claim 29 when frits are chosen from claim 29.

19. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 in view of Martin et al (USP 4,243,507).

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20. Bier set forth all the limitations of the claim, but did not explicitly recite the use of an isoelectric substance that is a combination of a weak acid and strong base (or strong acid and weak base). Martin discloses in an alternate isoelectric device that the most convenient means for achieving various pHs for each isoelectric compartment is to utilize a combination of a weak acid and strong base (or a strong acid and weak base) (col. 4, ll. 15-29). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Martin for the apparatus of Bier because the set forth acid and base combinations are the most convenient means for achieving selective pHs for isoelectric compartments.

21. Claims 35-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier in view of either Hearn et al (USP 4,279,724) or Söderberg (USP 4,334,972). Hearn and Söderberg are being utilized for the first time with this office action. Their use was necessitated by new claims 36-38.

22. With respect to claim 35, Bier set forth all the limitations of the claim, but did not explicitly recite the use of polymers containing amino and at least one other of the set forth groups. Söderberg teaches that Ampholine (i.e. the material utilized by Bier (col. 1, ll. 36-39)) comprises polymers of carboxylated imines. See col. 1, ll. 20-27. Carboxylated imines would comprise both amino groups and carboxyl groups thereby meeting the claim limitation. Hearn also teaches that Ampholine comprises polyamino-polycarboxylic acids. See col. 1, ll. 23-40. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of either Söderberg or Hearn for the ampholyte of Bier because Bier explicitly suggested using the specified ampholyte.

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23. With respect to claims 36-38, both Söderberg and Hearn also taught that the gap between pK and pI value should be as low as possible, including less than 1 pH unit. See col. 2, ll. 52-62 and col. 1, ll. 23-30 for Söderberg and Hearn respectively.

24. With respect to claim 42, a polyamino-polycarboxylic acid would presumably meet the broadly defined "non-natural amino acid" because any monomer or polymer containing both amino and carboxylate groups would constitute an amino acid.

25. Claims 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier in view of WO 92/15,870 (hereafter "WO '870").

26. With respect to claim 35, Bier set forth all the limitations of the claim but did not explicitly recite the use of an isoelectric substance from the claimed group. However, WO '870 teaches that polyamino- polycarboxylic acid is a conventional material utilized for forming an isoelectric substance (p. 2, l. 25 through p. 3, l. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '870 for the apparatus of Bier because the substitution of one known isoelectric substance for another requires only routine skill in the art.

27. With respect to claim 42, a polyamino-polycarboxylic acid would presumably meet the broadly defined "non-natural amino acid" because any monomer or polymer containing both amino and carboxylate groups would constitute an amino acid.

Response to Arguments

28. Applicant's arguments with respect to claims 27-53 have been considered but are moot in view of the new ground(s) of rejection necessitated by these new claims.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
August 1, 2005



KAJ K. OLSEN
PRIMARY EXAMINER